

REMARKS

Claims 4-6 and 18-22 are pending in the application. Claims 4-16 and 18-22 stand finally rejected. No claims are allowed.

Claim 4 has been amended to more particularly define the subject matter the Applicants consider their invention. Specifically, claim 4 has been amended to specify that the diameter of the outer surface of each portion of the stopper is less than or equal to the largest diameter of the inside surface of the distal end of the barrel having the contact area when the stopper is in the partially deflected position. Support for the amendment can be found throughout the specification and figures as originally filed, *e.g.*, page 8, paragraphs 28 and 30; Figures 4 and 9. Accordingly, no new matter has been introduced by this amendment.

Claims 4-6 and 18-22 are presented for further proceedings. Reconsideration of the claim rejections and allowance of the pending claims in view of the amendments above and the following remarks are respectfully requested.

Claim Rejections – 35 U.S.C. § 102

Claims 4, 21 and 22 stand finally rejected under 35 U.S.C. § 102(b) as allegedly anticipated by Trenner. Regarding claim 4, the only remaining independent claim, the Examiner states that Trenner discloses an IV flush syringe assembly (Figs. 1-14) comprising: a barrel (4) having an inside surface (30) defining a chamber (76) for retaining fluid, an open proximal end (6) and a distal end (8) including a distal wall (wall at 8) with an elongate tip extending distally therefrom having a passageway therethrough (46) in fluid communication with said chamber, said inside surface further including a contact area (32, 36) at the distal end of said barrel, a plunger (2) including an elongate

body portion (18) having a proximal end (22), a distal end (near 20) and a flexible stopper (Figs. 11-14, 100) slidably positioned in fluid-tight engagement with said inside surface of said barrel for drawing fluid into and driving fluid out of said chamber (col. 3, lines 35-40 disclose that the syringe is used for both aspiration and ejection of fluid) by movement of said stopper relative to said barrel, said elongated body portion extending outwardly from said open proximal end of said barrel (Fig. 12); wherein said contact area has a higher coefficient of friction than said inside surface outside of said contact area for frictionally engaging said stopper when said stopper is in contact with said distal wall of said barrel for frictionally holding said stopper in a partially deflected position to prevent reflux of the fluid back into the chamber after fluid has been delivered from said chamber.

According to the Examiner, the recess (32, 36) in Trenner creates a portion of the surface with a roughened surface area, the roughened surface area therefore having higher coefficient of friction than the smooth surface area of the rest of the inside of the barrel. The Examiner concludes that the roughened surface area provided by recess 32, 36 inherently helps prevent further movement of the plunger through frictional engagement with the stopper in the deflected position (as shown in Figure 13), since friction is inherently present in the contact between the stopper's rib and the recess 32, 36. The Examiner cites to the abstract of "Influence of Selfaffine Surface Roughness on the Friction Coefficient for Rubbers" from the Journal of Applied Physics (found online at <http://link.aip.org/link/?JAPIAU/94/5652/1>) as disclosing that the coefficient of friction for a material increases proportionally with the increase in roughness of the surface of the material. Therefore, according to the Examiner, the recess and the

cornered portion on either side of the recess at contact area 32/36 provides a roughness to the surface in that contact portion of the syringe barrel that the stopper does not experience contacting in the remainder surface portions of the inside syringe barrel surface which is smooth. Therefore, this contact area 32/36 provides an area with an increased coefficient of friction as compared to the smooth surface in the remainder of the barrel interior which frictionally engages the stopper (by frictionally engaging rib 108) and frictionally holds the stopper.

Applicants respectfully traverse this basis for rejection.

It has long been the law that a claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently, in a single prior art reference. *See Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 638, 631 (Fed. Cir. 1987). “To establish inherency, the extrinsic evidence ‘must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.’” *In re Robertson*, 169 F.3d 743, 745 (Fed. Cir. 1999) (citations omitted). In addition, for an anticipation rejection to be proper, the reference must clearly and unequivocally disclose the claimed subject matter or direct those skilled in the art to the claimed subject matter without any need for picking, choosing, and combining various disclosures not directly related to each other by the teachings of the cited reference. *See In re Arkley*, 455 F.2d 586, 587 (CCPA 1972); *Finisar Corp. v. DirecTV Group, Inc.*, 523 F.3d 1323, 1334 (Fed. Cir. 2008) (“But disclosure of each element is not quite enough – this court has long held that

‘[a]nticipation requires the presence in a single prior art disclosure of all elements of a claimed invention *arranged as in the claim.*’”) (quoting *Connell v. Sears, Roebuck & Co.*, 722 F.2d 1542, 1548 (Fed. Cir. 1983) (emphasis in original)).

Claim 4 (and thus claims 21 and 22) has been amended to specify that the diameter of the outer surface of each portion of the stopper is less than or equal to the largest diameter of the inside surface of the distal end of the barrel having the contact area when the stopper is in the partially deflected position. This is clearly shown in Figure 9, where each portion of stopper 54 has a diameter less than or equal to the largest diameter of the inside surface 132 of the distal end 130 of the barrel 122 having the contact area 162 when the stopper is in the partially deflected position. *See* pages 809, paragraph 0030. In this way, the contact area restrains the compressed stopper from moving in the proximal direction without any portion of the stopper interferingly fitting within any portion of the contact area of the barrel. Therefore, restraint of the compressed stopper is achieved entirely by frictional engagement – no mechanical interference is used.

In contrast, as acknowledged by the Examiner, the single use syringe disclosed in Figures 12 and 13 of Trenner shows the projecting portion 108 of plug means 26 received within annular groove 32 of barrel means 4. According to Trenner, “When the radially outwardly projecting portion 108 is seated in the annular groove 32, the slightly compressed plug means 26 will exert a force on the radially outwardly projecting portion 108 to ensure that it is firmly seated in the annular groove 32.” *See* col. 8, lines 19-23 (emphasis added). This type of “tongue and groove” interference fit is achieved because, as Trenner states, “the diameter of the generally cylindrical outer surface 110 [of

projecting portion 108] is slightly greater than the diameter of the inner surface 36 of annular groove 32 so that radially outwardly projecting portion 108 functions as a locking means.” *See* col. 7, lines 46-52 (emphasis added).

As such, rather than disclosing a stopper whose diameter of the outer surface of each portion is less than or equal to the largest diameter of the inside surface of the barrel, as required by the instant claims, Trenner discloses the complete opposite, namely a stopper whose diameter of the outer surface of the largest portion is greater than the largest diameter of the inside surface of the barrel. Thus, regardless of whether the contact area 32/36 of Trenner provides an area with an increased coefficient of friction as compared to the smooth surface in the remainder of the barrel interior, as the Examiner asserts, the syringe in Trenner cannot anticipate the claimed subject matter. *See Verdegaal*, 814 F.2d at 631.

Accordingly, Applicants submit that claims 4, 21 and 22 are not anticipated by Trenner, and reconsideration of this basis for rejection is respectfully requested.

Claim Rejections – 35 U.S.C. § 103

a. Claims 5 and 6 stand finally rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Trenner. According to the Examiner, Trenner discloses the device substantially as claimed including the contact area (32, 36) having an annular deformation (32 and 36 are a recess, i.e., an annular deformation). The Examiner acknowledges that Trenner does not disclose that there are a plurality of annular deformations, but asserts that it would have been obvious to one having ordinary skill in the art at the time of the invention was made to include multiple annular deformations,

since it has been held that mere duplication of the essential working parts of a device involves only routine skill in the art.

Applicants respectfully traverse this basis for rejection.

Claims 5 and 6 depend directly or indirectly from claim 4. Where an independent claim is valid over cited art, *a fortiori* any claim dependent therefrom must also be valid over the same art. *See Panduit Corp. v. Dennison Mfg. Co.*, 810 F.2d 1561, 1576 n.36 (Fed. Cir. 1987). As discussed above with respect to the rejection of claim 4, Trenner does not disclose a stopper whose diameter of the outer surface of each portion *is less than or equal to* the largest diameter of the inside surface of the barrel, but rather the complete opposite, namely a stopper whose diameter of the outer surface of the largest portion *is greater than* the largest diameter of the inside surface of the barrel.

Accordingly, for at least the reasons given above with respect to claim 4, Applicants submit that claims 5 and 6 are not unpatentable over Trenner, and reconsideration of this basis for rejection is respectfully requested.

b. Claims 18-20 stand finally rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Trenner in view of Lynn (US 5,522,804; “Lynn”). According to the Examiner,

Claims 18-20 depend from directly or indirectly from claim 4. Where an independent claim is valid over cited art, *a fortiori* any claim dependent therefrom must also be valid over the same art. *See Panduit Corp. v. Dennison Mfg. Co.*, 810 F.2d 1561, 1576 n.36 (Fed. Cir. 1987). As discussed above with respect to the rejection of claim 4, Trenner does not disclose a stopper whose diameter of the outer surface of each portion *is less than or equal to* the largest diameter of the inside surface of the barrel, but rather the

complete opposite, namely a stopper whose diameter of the outer surface of the largest portion is greater than the largest diameter of the inside surface of the barrel. Furthermore, the Examiner has pointed to nothing in Lynn that remedies these deficiencies of Trenner. As such, the combination of Lynn with Trenner cannot render the claimed invention obvious. *See In re Rijckaert*, 9 F.3d 1531, 1533 (Fed Cir. 1993).

Accordingly, for at least the reasons given above with respect to claim 4, Applicants submit that claims 18-20 are not unpatentable over Trenner in view of Lynn, and reconsideration of this basis for rejection is respectfully requested.

CONCLUSION

It is believed that claims 4-6 and 18-22 are now in condition for allowance, early notice of which would be appreciated. If any additional fees are due at this time, the Commissioner is authorized to charge Deposit Account No. 02-1666. Please contact the undersigned if any further issues remain to be addressed in connection with this submission.

Respectfully submitted,

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